# OFFICE OF RESEARCH COMPLIANCE - QUALITY REVIEW VISIT

## It's a wellness visit for your research!

### What is a Quality Review Visit?

The Office of Research Compliance (ORC) supports the TGH research community through world class quality assurance and research compliance support. The Quality Review Program (QRP) was developed to support researchers and improve the effectiveness and quality of their research. Through this, QRP helps ensure compliance with organizational policies and procedures, as well as applicable federal, state, and local laws.

To ensure quality conduct of research at TGH, the ORC has instituted an annual monitoring plan for human research projects at TGH. As a part of that plan, Quality Review Visits may be conducted on any research involving human subjects at TGH.

These Quality Reviews are intended to increase the level of protection for research participants by assessing adherence to IRB-approved protocols and can serve as an educational tool for researchers and research staff.

### What can you expect?

The Quality Review Visit will be completed by a Quality Assurance Monitor. Once scheduled the Quality Assurance Monitor will complete a review of the study's regulatory, clinical, and investigational product records as applicable. This process is completed through the Quality Review Checklist, which outlines the items being reviewed. Some of the focus areas that the Quality Assurance Monitor will be reviewing include:

- ✓ Regulatory Documentation
- ✓ Study/Subject Records
- ✓ Document Retention
- ✓ Sponsor Investigator Requirements

Next, the Quality Assurance Monitor will meet with the key study personnel to ask questions and discuss potential findings. To close out, the Quality Assurance Monitor will meet with the Principal Investigator (PI) to discuss a summary of the draft report.

A copy of the draft report and any recommendations for improvement will be provided to the PI. The PI will have an opportunity to respond to the draft report with any additional information or corrective action plans. If additional reporting to other internal or external departments or agencies is necessary, the Quality Assurance Monitor will work with the PI to complete that process.

Note: The Quality Review Visit does not replace or minimize the primary roles of the IRB and the PI for protecting human subjects. All reports/plans are for internal use only.

**Do you have concerns about a research study?** We can help! Upon request, we will provide a quick review consultation and can be requested at any time. If you have any questions about the program or concerns about a study, feel free to contact us.

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